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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,479	07/20/2007	Luigi Giusto Spagnoli	026073-00007	9687

4372 7590 02/01/2010  
ARENT FOX LLP  
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WASHINGTON, DC 20036

EXAMINER
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CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

NOTIFICATION DATE	DELIVERY MODE
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02/01/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/590,479	<b>Applicant(s)</b> SPAGNOLI ET AL.	
	<b>Examiner</b> Karen A. Canella	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Claims 1, 11 and 12 have been amended. Claims 1, 5-21 are pending and under consideration.

The instant application is a national stage application of PCT/IT05/00088, filed February 17, 2005. The PCT application discloses SEQ ID NO:1 as a 18-mer comprising the sequence "LANLTQ". The instant application discloses SEQ ID NO:1 as a 17-mer comprising the sequence "LANTQ". Thus, there is no support for the instant SEQ ID NO:1 in the parent international application. For purpose of examination, claims 1 and 5-21, reliant on the identity of SEQ ID NO: 1 will be given the effective filing date of July 20, 2007, said date being commensurate with the 371(c) date.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. When given the broadest reasonable interpretation, claims 1 and 11 include naturally occurring antibodies and peptides. Amendment to qualify the antibodies and peptides as "isolated" would overcome this rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Fogelman et al, (WO03/086326). Claim 11 is drawn in part to an immunogenic antigenic epitope of at least one

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human clusterin isoform comprising SEQ ID NO:4. Folgelman et al disclose the peptide of Sequence Identifier 20 (page 4, lines 1-2), said peptide comprising the instant SEQ ID NO:4 at residues 4-18. The peptide of Folgelman et al meets the requirement of being antigenic, as said peptide can be bound by an antibody. The peptide also fulfills the specific requirement of "immunogenic" as any peptide can be immunogenic given the appropriate host and appropriate presentation of the peptide to said host.

PN WO2006034056-A2.  
PD 30-MAR-2006.  
PF 16-SEP-2005; 2005WO-US033205.  
PR 16-SEP-2004; 2004US-0610711P.  
PA (REGC ) UNIV CALIFORNIA.  
PA (UYAL-) UNIV ALABAMA RES FOUND.  
PI Fogelman AM, Navab M, Anantharamaiah G;  
DR WPI; 2006-263401/27.  
PT New peptide containing D-amino acid(s) and/or protecting group(s),  
PT ameliorates symptoms of inflammatory conditions, e.g. atherosclerosis or  
PT stroke, in mammals.  
PS Disclosure; SEQ ID NO 478; 135pp; English.  
CC This invention describes a novel G-type peptide capable of ameliorating  
CC symptoms of an inflammatory condition, comprising AEG87480 and AEG87986  
CC and incorporating D amino acid(s) and/or protecting group(s). The  
CC invention also describes; a) a stent for delivering drugs to a vessel in  
CC a body comprising a stent framework including reservoir, and active  
CC agent(s) and/or a small organic molecule positioned in the reservoirs; b)  
CC a method of manufacturing a drug-polymer stent comprising providing a  
CC stent framework; c) cutting reservoirs in the stent framework; d)  
CC applying a composition comprising the active agent(s) to the reservoir(s)  
CC and drying the composition; e) a method of treating a vascular condition  
CC by positioning a stent within a vessel of a body; f) expanding the stent  
CC and eluting active agent(s) from a surface of the stent and g) a method  
CC of synthesizing a peptide comprising providing different peptide fragment  
CC subsequences of the peptide and coupling the peptide fragment  
CC subsequences in solution phase to form the peptide. The peptide comprises  
CC at least one and preferably all D amino acids and/or protecting group(s)  
CC at each terminus. It converts pro-inflammatory high density lipoproteins  
CC (HDL) to anti-inflammatory HDL or makes anti-inflammatory HDL more anti-  
CC inflammatory. The peptide It ranges in length from 3-10 or 6-37  
CC (particularly 18) amino acids and resembles a class A amphipathic helix  
CC of apolipoprotein J (ApoJ). The active agent includes class A amphipathic  
CC helical peptides, class A amphipathic helical peptide mimetics of apoA-I  
CC having aromatic or aliphatic residues in the non-polar face, small  
CC peptides including pentapeptides, tetrapeptides, tripeptides, dipeptides  
CC and pairs of amino acids, Apo-J and peptide mimetics. The active agent is  
CC contained within a polymer which comprises a first layer of a first drug  
CC polymer having a first pharmaceutical characteristic and the polymer  
CC layer comprising a second drug polymer having a second pharmaceutical  
CC characteristic. The stent framework comprises a metallic base or a  
CC polymeric base, especially a material consisting of stainless steel,  
CC nitinol, tantalum, MP35N alloy, platinum, titanium, a suitable  
CC biocompatible alloy and/or biocompatible polymer. The peptide used to  
CC ameliorate symptom(s) of an inflammatory condition e.g. atherosclerosis  
CC or stroke. It is used for; a) mitigating or preventing a coronary  
CC complication associated with an acute phase response to inflammation  
CC where the coronary complication is a symptom of atherosclerosis; b) for

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CC ameliorating a symptom of diabetes or inhibiting restenosis; c) as an  
 CC active agent useful in a stent for delivering drugs to a vessel in a  
 CC body, especially for treating a vascular condition. The peptide can be  
 CC used to treat the symptoms of atherosclerosis (e.g. hypertension, plaque  
 CC formation and rupture, reduction in clinical events such as heart attack,  
 CC angina or stroke, high levels of plasma cholesterol, high levels of low  
 CC density lipoprotein, high levels of very low density lipoprotein or  
 CC inflammatory proteins) as well as other inflammatory conditions e.g.  
 CC rheumatoid arthritis, lupus erythematosus, polyarteritis nodosa,  
 CC osteoporosis, alzheimer's disease and viral illnesses such as influenza  
 CC A. The peptide is highly stable and readily administered via an oral  
 CC route and can be used in the treatment of humans, non-human primates,  
 CC canines, equines, felines, porcines, ungulates and largomorphs. This  
 CC sequence represents an ApoJ G\* amphipathic helical domain peptide used in  
 CC the method of the invention.  
 XX  
 SQ Sequence 21 AA;

Query Match 100.0%; Score 73; DB 11; Length 21;  
 Best Local Similarity 100.0%; Pred. No. 0.00028;  
 Matches 15; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 METVAEKALQEYRKK 15  
 |||||  
 Db 4 METVAEKALQEYRKK 18

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al (European Journal of Biochemistry, 1994, Vol. 221, pp. 917-925). Wong et al disclose the amino acid sequence of human clusterin (page 919, figure 1A) wherein said amino acid sequence comprises the instant SEQ ID NO:2, 3 and 4 at residues 63-78, 93-112 and 431-445, respectively. The amino acid sequence of Wong et al meets the requirement of being antigenic, as said sequence can be bound by an antibody. The sequence also fulfills the specific requirement of "immunogenic" as any amino acid sequence can be immunogenic given the appropriate host and appropriate presentation to said host.

Claims 1, 5, 6, 11, 15-21 rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al (PNAS, 2000, Vol. 97, pp. 5907-5912).

Claim 1 is drawn to oligoclonal antibodies able to recognize and bind the antigenic epitope of at least one glycosylated cytoplasmic or non-glycosylated nuclear isoform of human clusterin, wherein the epitope of the non-glycosylated nuclear isoform is selected from a group including SEQ ID NO:2 and the non-glycosylated isoform is SEQ ID NO:3 or 4, and wherein the epitope is immunogenic. Claim 5 embodies the antibodies of claim 1 wherein the antibodies are

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tagged. Claim 6 specifies that the tag is a fluorochrome, a radioactive isotope, an enzyme, biotin or a chemiluminescent substance.

Claim 11 is drawn to an immunogenic antigenic epitopes of at least one human clustering isoform comprising SEQ ID NO:2, 3 or 4.

Claims 20 and 21 are drawn to a kit comprising at least one of the antibodies of claim 1.

Claim 15 is drawn to a method comprising the steps of protein extraction, incubation of the extracted protein with one of the antibodies of claim 1; qualitative and quantitative measurement of the antigen-antibody complexes.

Claim 22 is drawn to use of the antibodies of claim 1 for the qualitative and quantitative determination of the level of at least one isoform of human clusterin in a biological sample. Claim 24 specifies that the determination is carried out by ELISA, RIA, immunohistochemistry and Western blot.

Yang et al disclose a polyclonal antiserum raised by injection of bacterially expressed human clusterin into rabbits, wherein said antiserum is directed against nuclear, nonglycosylated clusterin and is used for immunofluorescence cell staining (page 5907, under "Antibodies") which meets the specific embodiment of claims 5 and 6, requiring a tag and a fluorochrome, respectively. The human clusterin of Yang et al meets the limitations of claim 11 as it reads on epitopes comprising SEQ ID NO:2, 3 and 4 which are inherently within the clusterin used by Yang et al for immunization of rabbits. Yang et al disclose that an immunological method for detecting the unglycosylated clusterin in nuclear lysates after exposure of the cells to radiation, by measuring binding of the polyclonal antibodies by Western blot, and immunoprecipitation, thus fulfilling the specific limitations of claim 19 and the limitation of claim 17 as requiring a sample which is a "liquor" because a nuclear lysate is a "liquor".

It is noted that the recitation of "for diagnosis of tumors and prediction of their malignancy grade" in claim 20 and the further limitation of specific tumors in claim 21 has not been given patentable weight because the recitation "for diagnosis of tumors and prediction of their malignancy grade" occurs in the preamble of claim 20. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See

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In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Because the intended use of diagnosing tumors in claim 20 is not given patentable weight, the recitation of the specific tumor types in claim 21 is also lacking patentable weight.

It is further noted neither that the limitation of claim 16 "for the diagnosis of tumors characterized by expression of clusterin and the prediction of their malignancy grade" nor the specific tumors as recited in claim 18 has patentable weight for the exclusion of prior art because the diagnosis of tumors and prediction of malignancy grade are processes of abstract reasoning. not requiring the transformation of matter. As clarified in In re Bilski, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir, 2008), a method claim must meet a specialized, limited meaning to qualify as a patent-eligible process claim and the test for such a method claim is whether the claimed method is (1) tied to a particular machine or apparatus, or (2) transforms a particular article to a different state or thing, summarized as the "machine or transformation test". In the instant case, recitation of "diagnosis of tumors characterized by expression of clusterin and the prediction of their malignancy grade" requires neither machine nor transformation beyond those of the active method steps of claim 15 and is therefore not patentable subject matter under 35 U.S.C. 101 and carries no further patentable weight within the context of the claim..

Given that the method of the prior art comprises the same method steps as claimed in the instant invention, , the claimed method is anticipated because the method will inherently be a method for diagnosis of tumor characterized by expression of clusterin and the prediction of their malignancy grade.. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 11-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Sullivan et al (Cell Death and Differentiation, 2003, vol. 10, pp. 914-927) in view of Wong et al (European Journal of Biochemistry, 1994, Vol. 221, pp. 917-925) and Maloy and Coligan ('Selection of Immunogenic Peptides for antisera Production', In: Current Protocols in Immunology, 1991, pp. 9.3.1-9.3.5, cited in a previous action).

O'Sullivan et al teach that in cells undergoing apoptosis after treatment with TNFalpha or ICI, clusterin can be detected in the nuclear fraction as a non-glycosylated, uncleaved isoform (page 922, bridging paragraph, column 1 to column 2). O'Sullivan et al teach that during normal synthesis and secretion, clusterin is translocated to the lumen of the ER where it is folded and glycosylated (page 921, first column, lines 1-5). O'Sullivan et al teach that human clusterin has six N-linked glycosylation sites including alpha-81N (page 914, lines 28-31). O'Sullivan et al teach that it was not possible to distinguish if the nascent clusterin was not glycosylated as a result of the TNFalpha or ICI treatment, or if glycosylated clusterin was deglycosylated prior to retrograde transport to the ER and then the nucleus (page 922, second column, lines 2-9).

Wong et al teach the sequence surrounding the six glycosylation sites in human clusterin including alpha-81N, which is the second glycosylation site indicated in Figure 1A and includes the instant SEQ ID NO:2.

Maloy and Coligan teach that the length of the peptide of about 15 residues can be used to make an antisera that will react with the native protein (page 9.3.3, under the heading "Selection of the Length of the Peptide").

It would have been prima facie obvious at the time that the claimed invention was made to raise antibodies using pairs of peptides representing the glycosylation sites of clusterin indicated in Wong et al, wherein said peptide pair comprised a glycosylated peptide and a non-



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glycosylated peptide, thus providing a polyclonal antiserum which binds to the epitope of the instant SEQ ID NO:2 when both glycosylated and non-glycosylated. One of skill in the art would have been motivated to do so in order to have antibodies that bind to clusterin at specific epitopes that were either glycosylated or non-glycosylated. One of skill in the art would understand that having antibodies which can map the glycosylation or non-glycosylation of the clusterin protein can further the understanding of the processing and function of the clusterin. It would have been further obvious to use the art-recognized procedure of Maloy and Coligan to raise the antibodies in order to obtain an antiserum that will bind to the native protein.

Claims 1, 5-8, 10-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Sullivan et al (Cell Death and differentiation, 2003, vol. 10, pp. 914-927) in view of Wong et al (European Journal of Biochemistry, 1994, Vol. 221, pp. 917-925) and Maloy and Coligan ('Selection of Immunogenic Peptides for antisera Production', In: Current Protocols in Immunology, 1991, pp. 9.3.1-9.3.5). as applied to claims 1, 5, 11-18, 20 and 21 above, and further in view of Kerr and Thorpe (Immunochemistry LabFax, 1994, pages ix-x, 118, 134-135, 142-143, 158-161).

Claim 6 embodies the antibodies of claim 65, wherein the antibodies are tagged with a fluorochrome, radioactive isotope, enzyme, biotin or a chemiluminescent substrate. Claim 7 specifies that said fluorochrome is selected from the group consisting of fluorescein, ficoltrine, rhodamine, texas red and cumarine. Claim 8 specifies that said isotope is 14-C or 3-H. Claim 10 specifies that the enzyme is horseradish peroxidase or alkaline phosphatase.

Kerr and Thorpe et al teach common methods in immunoassays, and commonly used antibody labeling tags including fluorochromes (pp. 158-161), isotopes (page 118) and the enzymes horseradish peroxidase (pp. 134-135) and alkaline phosphatase (pp. 142-143).

It would have been prima facie obvious at the time that the claimed invention was made to label the antibodies rendered obvious by the combined teachings of O'Sullivan et al, Wong et al and Maloy and Coligan with fluorochromes, isotopes, horseradish peroxidase or alkaline phosphatase. One of skill in the art would have been motivated to do so because these were tags commonly recognized in the art to be useful in labeling antibodies.

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Claims 1, 5, 6, 9, 10-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Sullivan et al (Cell Death and differentiation, 2003, vol. 10, pp. 914-927) in view of Wong et al (European Journal of Biochemistry, 1994, Vol. 221, pp. 917-925) and Maloy and Coligan ('Selection of Immunogenic Peptides for antisera Production', In: Current Protocols in Immunology, 1991, pp. 9.3.1-9.3.5). as applied to claims 1, 5, 11-18, 20 and 21 above, and further in view of Scheele et al (U.S. 5,663,315).

Scheele et al teach common methods for labeling and detecting antibodies include the use of radioisotopes, fluorophores, horseradish peroxidase and luciferin (column 5, lines 12-34).

It would have been prima facie obvious at the time that the claimed invention was made to use radioisotopes, fluorophores, horseradish peroxidase or luciferin for tagging the antibodies rendered obvious by the combined teachings of O'Sullivan et al, Wong et al and Maloy and Coligan. One of skill in the art would have been motivated to do so because these were tags commonly recognized in the art to be useful in labeling antibodies.

Applicant argues that given the Declaration of Dr. Spagnoli, one of skill in the art would not have been able to modify the teachings of Danik, Karon and Maloy to arrive at the presently claimed invention. The Declaration states that a person skilled in the art, having the disclosures of Lakins and Kerr, would not be able to combine the disclosures to arrive at the presently claimed invention, and would consider the level of sensitivity and specificity achieved by the antibodies of the presently claimed invention unexpectedly high. This has been considered and found partially persuasive with regard to the particular disclosures of Lakins and Kerr. However it is noted that the instant claims do not require a particular sensitivity or specificity. It is further noted that Section 2144 of the M.P.E.P. states:

*The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant.*

Thus, the motivation provided by the combination of O'Sullivan, Wong and Malloy would provide for antibodies that bind the same epitope as the instant SEQ ID NO:2 and said

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antibodies would be expected to have the same specificity as the instant antibodies, and therefore the same sensitivity as the instant antibodies, said specificity and sensitivity being governed by the absence of cross-reacting epitopes. Thus the specificity of said antibodies to SEQ ID NO:2 would reflect the targeted epitope rather than a particular structural feature of the claimed antibodies.

All claims are rejected.

All other rejections and objections as set forth or maintained in the prior Office action are withdrawn in light of the Declaration of Dr. Spagnoli, filed April 9, 2009..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643

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